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May 25, 1999

Dr. Elizabeth A. Yetley, Ph.D., Director OSN/CFSAN
USA Delegate to Joint FAO/WHO Codex Alimentarius
Committee on Nutrition & Food for Special Dietary Use
200 C Street South West, #HFS-456, City of Washington
District of Columbia, United States of America 20204

RE: Comments on Draft Policy Paper,
Scientific Risk Management Model
For Foods for Special Dietary Use
U.S./F.D.A. Docket #99N-0391

Dr. Yetley,

During the 23rd session of the CCNFSDU last Fall in Berlin, you, along with the Canadian and EC delegates, volunteered to draft position papers for use by CCNFSDU Committee Delegates and their respective governments. The purpose of the papers are to define and explain the rationale, and scientific basis, behind the two divergent viewpoints on developing guidelines for establishing safe upper limits for nutrient amounts (potencies) in fortified foods and dietary supplements.

This letter is to provide comments as input for you in this important work. There are several sources of published documents that you can reference for your work to provide a strong base from which the US position can be validated and advocated:

I. The published **Principles and Guidelines already Approved by the CAC** and relevant committees..

A) CAC Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account:

1. "... shall be based on the principles of sound scientific analysis and evidence..."
2. "... promotion of fair practices in food trade..."

B) Joint FAO/WHO Consultation in January 1997 (FAO Food and Nutrition - Report 65) General Principles of Food Safety Risk Management:

Principle 1. Risk Management should follow a structure approach: " ... Evaluation > Option Assessment > Decision Implementation > Monitoring & Review "

Principle 2. Protection of Human Health should be the Primary Consideration in Risk Management Decisions "...arbitrary or unjustified differences in the risk levels s should be avoided...Consideration of ...benefits...and societal preferences may be appropriate...and should not be arbitrary and should be made explicit."

Principle 3. Risk Management Decisions should be Transparent:"...documentation of... decisions making, so that the rationale is transparent to all interested parties."

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Principle 5. Functional Separation of Risk Management and Risk Assessment.
"...separation... serves to ensure the scientific integrity...and reduce conflict of interest."

Principle 7. Risk Management should include: "... communications with consumers and other interested parties...reciprocal communication among all interested parties is an integral part...a major function is the process by which information and opinion ... is incorporated into the decision."

Principle 8. Continuing Process that takes into Account all Newly Generated Data
...periodic evaluation of the data ...to determine its effectiveness in meeting food safety objectives."

II. The **Articles and Principles from the General Agreement on Trade and Tariff (GATT-1947)**

Article XX: General Exceptions: "... measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries...or a disguised restriction on international trade."

III. The **Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement):**

"...Measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination... or a disguised restriction on international trade..."

Article 2: Basic Rights and Obligations:

1. "...applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence..."

2. " ...Do not arbitrarily or unjustifiably ... shall not be applied in a manner which would constitute a disguised restriction on international trade."

3. " ...Be in accordance with the obligations of the Members under the provisions of GATT..Article XX

Article 3: Harmonization:

1. "...base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist."

2. "Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994."

3. "Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than relevant international standards, guidelines or recommendations, **if** there is a scientific justification, or ...Shall not be inconsistent with any other provision of this Agreement."

4. " Members shall play a full part, ... in particular the Codex Alimentarius Commission, To promote within these organizations the development and periodic review of standards, guidelines and recommendations..."

Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection:

1. "...Measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations (e.g.: Codex)."

2. "...Take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases ..."

4. "...Take into account the objective of minimizing negative trade effects."

5. " With the objective of achieving consistency...against risks... avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on International trade. Members shall cooperate...to develop guidelines... take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves."

6. "... Ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility." *[Footnote 3: For purposes of paragraph 6 of Article 5, a Measure is not more trade-restrictive than required unless there is another measure, reasonably available, taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.}* "

7 " In cases where relevant scientific evidence is insufficient, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

8. " When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards guidelines or recommendations or such standards, guidelines or recommendation do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure."

IV. The published **Risk Assessment reports of various authorities and recognized experts**:

A) Recommended Dietary Allowances (10th Edition, 1989) – Food and Nutrition Board, Commission on Life Sciences, national Research Council, National Academy of Sciences
B) A scientific Evaluation of the Range of Safe Intakes – Vitamins and Minerals– Dr. Derek Shrimpton, Ph.D. – commissopmed by the European Health Product Manufacturers Association (EHPM) (1997)
C) " Vitamin & Mineral Safety" – Dr. John Hathcock, Ph.D., Science Director, Council For Responsible Nutrition-U.S.A. (1997)
D) A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients– Food And Nutrition Board, Institute of Medicine, National Academy of Sciences (1998)

V. Public **Statements from U.S. authoritative bodies:**

A) The findings of Congress included as preamble to the Dietary Supplements Health and Education Act (1994)
B) The 1998 report of the National Institute of Health, Center for Alternative and Complementary Medicine
C) The 1997 Report of the Presidential Commission on Dietary Supplement Labeling

These documents will, collectively, provide powerful support for the U.S. position advocating science based risk assessment to establish guidelines for upper safe limits of nutrients in foods and supplements. In addition to the points made in the documents referenced there are several other compelling arguments in support of our position:

- **Health need**: to supplement the diet, using US government surveys validating the fact that Americans are "overfed but undernourished" and consume less than even minimal RDA amounts of key nutrients (ref: Recommended Dietary Allowances 1989 – Food & Nutrition Board, Commission on Life Sciences, National Research Council)
- **Consumer preference**: citing surveys indicating that a majority of Americans use dietary supplements, even in the absence of reimbursement or government recommendation (ref: Economic Characterization of the Dietary Supplements Industry, 1999 – commissioned by USFDA/CFSAN from the University of North Carolina)
- **Lower health care costs**: using just the recently published studies from Australia and the U.S.A., validating the monetary cost savings available from consistent use of dietary supplements. (ref: American Journal of Cardiology {1998-82:414-417} & Western Journal of Medicine {1997-166:306-312})
- **Risk/benefit ratio**: using the verified risks (ref: USFDA/CFSAN/OSN/AEMS) versus the validated benefits (ref: NRC's RDAs-10th Ed.), and especially when compared to the same ratio for government approved over-the-counter and prescription drugs (ref: USFDA/MedWatch).

In addition to the above comments, you specifically requested comments on eight key points, to provide guidance to "identify the range of perspectives associated with the manufacture, use, and regulation of vitamin and mineral supplements (sic)". You also specifically requested that these comments:

- provide a neutral and objective presentation on the issues
- help understand the rational behind the different approaches
- be useful to study in depth the principles justifying each particular position in order to find a common ground for discussion

We hope the following comments provide such input.

Point 1.Terminology:

We recommend that the terminology used to describe these food products be **dietary supplement,** because it is more inclusive and more descriptive than other options. The other support for use of the term dietary supplement is the inference that such a supplement may be valuable to ensure a comprehensive and complete intake of all essential nutrients as part of overall dietary intake.

The term nutritional supplement, or the term vitamin & mineral supplement, may inadvertently and unnecessarily preclude non-nutrient, but nevertheless desirable, ingredients – such as choline. The term food supplement has a connotation similar to dietary supplement and would be a secondary choice, except that it may also inadvertently preclude non-nutrient ingredients as components.

Point 2. Purpose & Role:

We strongly recommend that all-possible legitimate, responsible and scientifically supportable purposes and roles of dietary supplements be included. Deficiency disease prevention, nutrient supplementation of restricted diet, nutritional fortification, disease risk-reduction, physiological benefit, optimal physical and/or mental performance and foods for special dietary use are all examples of such scientifically supportable purposes and roles.

Point 3. Approved Nutrients:

We **very strongly** recommend that NEITHER a positive nor a negative list of ingredients for dietary supplements be proposed, advocated, developed or approved. Given the wide variation in nutritional requirements and dietary intakes for different nations (and sub-populations, age and gender groups within those nations) such lists would be difficult, if not impossible to be both inclusive and universally valuable as an authoritative reference.

Although a universally acceptable list of ingredients approved for inclusion in dietary supplements is theoretically possible to develop, we especially recommend against a list of unapproved (negative) ingredients. Such a list may, for instance, fail to account for specific individuals and even entire population sub-groups who may have a nutritional or physiological need to supplement their diet with an ingredient that may be harmful for the majority of the population. Supplemental Flouride for children, but not for adults, and Iron for menstruating women, but not for some men, are both classic examples.

Virtually all national authorities, as risk managers for protecting public health and safety, have laws and regulations that provide authority to restrict or prohibit dietary ingredients that present, by their inclusion in dietary supplement, an unacceptable risk to human health and safety. Such authority is adequate and does not need an internationally developed "positive" list to be effective.

Point 4. Maximum Levels:

We **very strongly** recommend that guidelines for maximum allowable levels of ingredients for use in dietary supplements **NOT** be proposed, advocated, developed or approved. Given the wide variation in nutritional requirements and dietary intakes for different nations (and sub-populations, age and gender groups within those nations) such levels would be difficult, if not impossible to be both inclusive and universally valuable as authoritative references.

Although universally acceptable numbers for maximum allowable levels of ingredients for inclusion in dietary supplements are theoretically possible to develop, we especially recommend against developing such levels. Such levels may, for instance, fail to account for specific individuals and even entire population sub-groups, who may have a nutritional or physiological need to supplement their diet with a dietary ingredient at a level that may be harmful for the majority of the population. Selenium levels dependent on geographical location and diet, and Vitamin D levels dependent on weather, diet and lifestyle are both classic examples.

Virtually all national authorities, as risk managers for protecting public health and safety, have laws and regulations that provide authority to restrict the levels of dietary ingredients present in a dietary supplement, if they pose a validated and unacceptable risk to human health and safety. Such authority is adequate and does not need internationally developed maximum allowable levels to be effective.

Given the fact, however, that such guidelines are a current topic in the C.C.N.F.S.D.U., and given that the only realistic alternative to guidelines based on policy is to help develop guidelines based on science, we recommend development of science-based risk assessment guidelines as the preferable choice. Such guidelines would, however. Be unenforceable in the U.S.A., as they would contravene the Food Drug & Cosmetics Act, as amended by the D.S.H.E.A. of 1994

Point 5. Minimal Levels:

With reservations, we cautiously recommend that guidelines for minimal permissible levels of dietary ingredients for use in dietary supplements be proposed and discussed. Given the wide variation in nutritional requirements and dietary intakes for different nations (and sub-populations, age and gender groups within those nations) such levels would be difficult, if not impossible to be both inclusive and universally valuable as authoritative references.

Although universally acceptable numbers for minimal permissible levels of dietary ingredients for inclusion in dietary supplements are theoretically possible to develop, such levels would be extremely difficult to develop and scientifically justify. Such levels may, for instance, fail to account for specific individuals, and even entire population sub-groups, who may have a nutritional or physiological need to supplement their diet with a dietary ingredient at a level greatly in excess of the level determined to be minimally essential for the majority of the population. Calcium levels dependent on age, diet and sex, and Folate levels dependent on reproductive status and diet are both classic examples.

Virtually all national health authorities, as risk managers for protecting public health and safety, have laws and regulations that provide authority to define a dietary supplement, partially, if not wholly, dependent on its nutritional content. Such authority may prove adequate to protect consumers against developed minimal permissible levels to be effective.

Point 6. Purity and G.M.Ps:

We cautiously recommend that guidelines for manufacturing, packaging, labeling and storage of dietary supplements be developed. Such guidelines would be helpful towards ensuring that dietary supplements sold to consumers are safe and effective, as defined by label information. Such guidelines must also be based primarily on food manufacturing practices, not on drug manufacturing practices. The risks associated with poorly manufactured dietary supplements are even less than those associated with poorly manufactured foods (less bacterial contamination), and considerably less than those associated with poorly manufactured drugs (less pharmacological impact).

The key factors, which should be included in guidelines for Good Manufacturing Practices for Dietary Supplements, should be comprehensive, and include, at a minimum:

Certification those personnel are qualified and trained to manufacture dietary supplements
Formulation certification
Ingredient verification (including ingredient purity certification)
Dosage consistency
Activity/potency and shelf-life certification
Activity/potency and overage certification
Certification of acceptable contaminants levels
Certification of acceptable purity (e.g. that the product actually produced contain ingredients, and ingredient amounts, as specified in the original formulation; and the product is pure and uncontaminated , within specified guidelines, as per appropriate procedural processes and physical assays based on appropriate methods.)
Packaging certification: packaged to ensure shelf life and to protect contents and consumers
Labeling certification: clear, complete, comprehensive, accurate, truthful and non-misleading
Certification that all practices are followed, and specifications observed, as written

We are only cautiously recommending such development, at this time, because final regulations for dietary supplement G.M.P.s have yet to be issued by your agency. If, and when, such regulations are finalized and published, we will review them and determine if such regulations should be supported, or opposed, in international arenas such as Codex.

Point 7. Labeling, Warning Statements, and Claims:

We strongly recommend that guidelines be developed for the labeling of dietary supplements, while recognizing the difficulty inherent in developing guidelines universally acceptable, even appropriate, for the diverse needs of different peoples and nations. Some key elements, however, which should be included in any guidelines developed, are:

- Full Disclosure Ingredients list, including all excipients
- Clear and comprehensive product name/description
- Comprehensive and Consistent Nutritional Facts information
- Suggested use information, including specific daily dosage
- Consumers Safety Statements: (must be based on sound science and public health factors)
  - warnings, highlighted for maximum consumer impact
  - cautions, emphasized for consumer notice
  - contraindications, emphasized for consumer notice
  - interactions (foods <> supplements <>drugs), emphasized for consumer notice
- Clear, indelible, lot/batch control numbers
- Expiration/Best Before dating (based on delivering 100% of claimed label potency)
- Product code identification numbers
- Consumer Benefit Statements: (must be scientifically validated)
  - As approved classic nutrient deficiency statements
  - As physiological "structure/function" statements
  - As authoritative disease risk-reduction health claims

Contact information for product supplier (as determined by national authority)

As a universal and overriding point regarding labeling, **all** information contained on or in a label or labeling MUST be truthful and non-misleading, and MUST be certified as accurate and complete.

Point 8. Packaging and Marketing:

Although we recommend that guidelines be developed for the packaging of dietary supplements, we recognize the difficulty inherent in developing guidelines universally acceptable, even appropriate, for the diverse needs of different peoples and nations. Some Key factors, however, that should be included in any guidelines developed, are:

Specification of a package, and packaging compoments, that will:

> Retain the product potency / activity through the expiration/best before date,
> Protect children from those products that may pose a health risk to children
> Safeguard the product from environmental contamination
> Provide evidence of tampering with the integrity of the product or the package

SUMMATION:

The history of modern dietary supplements is less than a century old, although crude forms have been used since pre-historic times. During this century, science has continued to validate the safety and benefits of supplementing nutrients, both at RDA levels, and at "optimal" dosages, considerably higher. After a century of consumer use, and a plethora of toxicity and safety studies, the US government has frequently, in order to fulfill its consumer protection mandate, proposed restricting the sale of nutrients based on safety concerns over excess consumption levels (1938, 1976, 1992). Such proposals have yet to engender restrictions beyond Potassium in pill form and the packaging of Iron containing dietary supplements.

If the CCNFSDU continues pursuing Maximum Upper Safe Nutrient Levles, we urge you to strongly advocate for consistent application of CAC mandated, science based, Risk Analysis and Risk Management methods to determine those levels. We also encourage you to emphasize the importance of an *evidence-based* system, rather than a *policy based* system. Good government, like good science, is based on fact, not opinion, and we encourage you in your efforts to support, and advocate, the benefits of the D.S.H.E.A. for health conscious consumers worldwide. We look forward to working with you in support of the US position on this issue, in Rome this summer, and in Berlin next year.

Regards & Health,

Karl Riedel
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cc: Mr. Michael Q. Ford, Executive Director -National Nutritional Foods Association (NNFA), Mr. Charles Raubicheck & Mr. Anil Abraham, Sidley & Austin – Counsel for the NNFA, Mr. Simon Pettman, Executive Director -International Alliance of Dietary Supplement Associations (IADSA).

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